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In the Supreme Court of the United States

October Term, 1983

KATHLEEN HASLER and MICHAEL HASLER,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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March 16, 1984

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60 pp

QUESTIONS PRESENTED

1. Whether on review of a trial court's findings the Court of Appeals is free to decide factual issues *de novo*?

2. Whether on review of a trial court's findings, the Court of Appeals can require a higher standard of proof on the issue of causation than is required under the Federal Tort Claims Act, 28 U.S.C. secs. 1346(b), 2071-2680, and the Swine Flu Program Act of 1976, 42 U.S.C. sec. 247b (1976)?

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The Petitioners, KATHLEEN and MICHAEL HASLER, respectfully pray that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Sixth Circuit entered in this proceeding on October 7, 1983.

OPINION BELOW

The opinion of the Court of Appeals, reported in 718 F.2d 202 (6th Cir., 1983), appears in the Appendix hereto. The opinion of the District Court for the Eastern District of Michigan, Southern Division, reported in 517 F. Supp. 1262 (1981), appears in the Appendix hereto.

JURISDICTION

The judgment of the Court of Appeals for the Sixth Circuit was entered on October 7, 1983. A timely petition for rehearing *en banc* was denied on December 22, 1983 and this petition for certiorari was filed within 90 days of that date. This Court's jurisdiction is invoked under 28 U.S.C. sec. 1254(1).

STATUTORY PROVISIONS INVOLVED

United States Code, Title 28:

Section 1346(b). United States as Defendant.

> (b) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on or after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under the circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

United States Code, Title 28, Chapter 171 - Tort Claims Procedures:

Section 2674. Liability of United States.

> The United States shall be liable, respecting the provisions of this title relating to tort claims, in the

same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.

If, however, in any case wherein death was caused, the law of the place where the act or omission complained of occurred provides, or has been construed to provide, for damages only punitive in nature, the United States shall be liable for actual or compensatory damages, measured by pecuniary injuries resulting from death to the persons respectively, for whose benefit the action was brought, in lieu thereof.

The Swine Flu Program Act of 1976, Title 42:

Section 247b(k)(2).

(2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent that the United States would be liable in any other action brought against it under such sec. 1346(b) and chapter 171, except that—

(i) the liability of the United States arising out of the act or omission of a program participant may be used on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort and breach of warranty.

STATEMENT OF THE CASE

The Swine Flu Immunization Program of 1976 was an attempt, underwritten by the Federal Government, to inoculate the entire population of the United States against swine flu.

The Swine Flu Program Act of 1976, 42 U.S.C. sec. 247b established the claim procedure for individuals who experienced harmful reactions to the swine flu vaccinations. The Swine Flu Act delineates the legal remedies available for these injured persons. The Act creates a cause of action against the United States for any personal injury or wrongful death sustained as a result of the swine flu inoculation caused by the act or omission of a program participant based on any theory of liability that would govern in an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort and breach of warranty. Here, Michigan law applies.

The Swine Flu Act makes that cause of action the exclusive remedy and abolishes the cause of action against the program participants i.e., the vaccine manufacturers, etc. and makes the procedures of the Federal Tort Claims Act applicable to suits brought pursuant to the Swine Flu Act.

Petitioner, KATHLEEN HASLER, then 27 years old, received a swine flue inoculation pursuant to the Swine Flu Immunization Program of 1976 on November 24, 1976. Ten days thereafter she developed a sudden and severe systemic reaction characterized by high spiking fever, hematinuria (red blood cells in her urine), kidney involvement, skin rash, and pain and limitation of her joints. All of the major joints of her body were affected, eventually resulting in extensive joint destruction.

Petitioner brought suit against the United States for its own negligence under the Federal Tort Claims Act and for negligence and breach of warranty (strict liability) of the program participants under the Swine Flu Act.

At trial, Petitioner presented the testimony of three physicians as expert witnesses on the issue of causation. The United States countered with four physicians who testified as its experts. The trial court stated in its opinion:

> The task of the court in weighing the testimony of these physicians, *all of whom are competent and reputable* is a difficult one. 517 F. Supp. at 1270 (emphasis added).

The Petitioner's expert included the treating physician, Edmund M. Barbour, M.D. He testified that Mrs. Hasler's disease process did not behave like any he had seen in his ten years of private clinical practice and in his affiliation with Wayne State University. He further testified that she had an unusual inoculation (swine flu vaccine) ten days before the onset of symptoms. At the exact time when you would have expected an immunological event to occur, a healthy woman developed a severe systemic reaction, characterized by an immunologic response and a typical antibody reaction. In Dr. Barbour's expert opinion the swine flu vaccine had caused the severe joint destruction and disease process Mrs. Hasler suffers from to this day.

Dr. Barbour testified that Mrs. Hasler's family history was in essence totally negative. This information shows a strong family background of good health and is another factor Dr. Barbour relied upon when he concluded that Mrs. Hasler was suffering a reaction from the swine flu vaccine.

Dr. Barbour further testified that Mrs. Hasler's condition differs from rheumatoid arthritis in several significant ways.

First, rheumatoid arthritis usually responds to certain antigens and the rheumatoid factor in the blood is usually positive. This is not the case with Mrs. Hasler. Secondly, rheumatoid arthritis usually burns itself out in a period of time or at least is controlled by one of the major modalities of treatment. This is not the case here. Other factors distinguishing Mrs. Hasler's condition from rheumatoid arthritis include:

- Mrs. Hasler's high fever persisted for an expanded period of time.
- The joint involvement was more severe than usual.
- Mrs. Hasler developed hematinuria.
- She had kidney involvement.
- She had a heart murmur.
- She had a skin rash similar to the rash seen in rheumatic fever, but not in rheumatoid arthritis.

When these clinical factors are combined and then viewed in relation to the temporal onset of this disease, Dr. Barbour concluded that the swine flu vaccine was the causative factor of Mrs. Hasler's disease process. Dr. Barbour stated that in his opinion, *based upon a reasonable degree of medical certainty* the swine flue shot did cause Mrs. Hasler's disease process. (Record at 33-34).

Plaintiff next introduced the testimony of William G. McDonald, M.D., a specialist in rheumatology. He testified that in his opinion based upon his examination, treatment of the patient and review of the medical records, that *to a reasonable degree of medical certainty,* Mrs. Hasler's illness was probably incident to the swine flu vaccine

she received shortly before the onset of her illness. (Record at 122).

Plaintiff also relied at trial on the deposition testimony of Anthony J. Sliwinski, M.D., head of the Department of Rheumatology at Georgetown University Hospital. Dr. Sliwinski reviewed the medical records of Kathleen Hasler from December 3, 1976 through March 14, 1980. Dr. Sliwinski found when he went through the medical records that Mrs. Hasler appeared to be perfectly healthy, received an immunization (swine flu vaccine) and sometime thereafter developed a febrile illness with polyarthritis.

Dr. Sliwinski testified that initially Petitioner's laboratory studies were normal, but thereafter she had evidence of red blood cells in her urine indicative of the fact she was having an immune disease in her kidneys. She developed protein in her red blood cells. Both of these findings are not usually a part of rheumatoid arthritis or Still's disease and are indicative of an immune injury occurring in the patient.

Dr. Sliwinski opined that by far the most likely cause of Mrs. Hasler's condition was the swine flu vaccination she had received.

Dr. Sliwinski based his opinion on several factors:

- She was perfectly normal, received a swine flu vaccine, a potent immunigen, and within 10 days or so at the time an immune reaction is expected to occur, she became acutely ill.
- There is no medical evidence that this was a chronic problem which was just manifesting itself.
- She had evidence of widespread auto-immune disease.
- Fever, involvement of the skin, joints and kidneys implied an immune injury was occurring of the auto-immune kind.

Dr. Sliwinski conceded that generally speaking, the cause of rheumatoid arthritis or Still's disease is unknown. However, in Mrs. Hasler's specific case, he did say *to a reasonable degree of medical certainty* that the swine flu vaccine was the cause of her disease. (App. 911-912).[1]

On the other hand, the physicians who testified for the Government characterized Mrs. Hasler's condition as the adult onset of juvenile rheumatoid arthritis (Still's disease). They further testified that she met a sufficient number of the criteria of the American Rheumatism Association to have rheumatoid arthritis. These doctors testified that the cause of Still's disease and rheumatoid arthritis is unknown. Nevertheless, all the defense doctors stated in their opinion the Swine flu vaccine had nothing whatsoever to do with Plaintiff's illness.

The trial court summarized the defense medical testimony as follows:

> All physicians who testified for the defense said that they didn't know the cause of Still's disease or rheumatoid arthritis, but that the swine flu vaccine did not cause them.
>
> Their syllogism seems to be:
>
> 1. Plaintiff has rheumatoid arthritis.
>
> 2. No one knows the cause of rheumatoid arthritis.
>
> Therefore: Swine flu vaccine cannot cause rheumatoid arthritis. The syllogism speaks for itself.

517 F. Supp. at 1271 n.2.

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1. Dr. Sliwinski testified at trial via introduction of his deposition. Since this was a bench trial the deposition was not read into the record. The Appendix pages referenced above refer to his deposition which was part of the Joint Appendix on Appeal to the Sixth Circuit.

In deciding the issue of causation in the Petitioners' favor the trial court stated:

> Several things impressed the Court and impel a conclusion that the Plaintiff has carried her burden by a fair preponderance of the evidence by showing that the swine flu shot did indeed cause her arthritis.
>
> First of all, the onset of the disease was within the time limits for such type of immunological reaction. Temporally the reaction started in "text book manner." This was agreed to by all physicians.
>
> Secondly, Plaintiff's reaction was a typical antibody and immunological response which usually develops 7 to 10 days after a shot is given.
>
> Third, tests given upon admission to the hospital were all normal, but subsequently there was a high spiking fever, rash, anemia, heart murmur and an inflammatory process throughout the entire body. Moreover, every physician agreed that rheumatoid arthritis can be related to an antibody antigen reaction.
>
> Finally, the negative health history of the Plaintiff and her family are significant to the conclusion that the swine flu shot was the causative factor of the plaintiff's disease.
>
> In view of the fact that there were symptoms other than those found in the normal case of Still's disease, namely rash, anemia, heart murmur, protein and blood in the urine, and because rheumatoid arthritis can result from an antibody antigen reaction and there was no significant medical history related to rheumatoid arthritis, it is reasonable for this court to find as a matter of fact that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is especially

> true in view of the temporal relationship - the sudden onset of the disease 10 days after the swine flu shot - a fact which cannot be regarded by this Court as mere coincidence.

517 F. Supp. at 1271.

Further, the trial court decided that as a matter of fact under Michigan law of either negligence, implied warranty or strict liability, the United States breached its duty of providing an adequate warning of the possible potential dangers of the swine flu vaccine. The trial court found that the Petitioners were entitled to damages totalling $1,550,000.00.

The judgment of the District Court in Petitioners' favor was reversed by the Court of Appeals on the sole ground that the trial court's decision on the factual issue of causation was mere conjecture. The Court of Appeals held:

> The record shows only two facts with certainty: (1) a swine flu inoculation protects an individual from flu by causing an immunological reaction; and (2) rheumatoid arthritis may be considered an auto-immune disorder. The plaintiff has failed to present any theory linking these facts to show that her immunological reaction to swine flu caused the auto-immune disease from which she suffers.
>
> We find any causal connection between the swine flu inoculation and plaintiff's rheumatoid arthritis merely conjectural. Although her explanation is consistent with known facts, Mrs. Hasler has not shown that her injury flows in logical sequence from the defendant's conduct.

718 F.2d at 206.

REASONS FOR GRANTING THE WRIT

1. The Decision Below Conflicts With Decisions of This Court, Other Decisions of the Sixth Circuit and Decisions in Other Circuits Concerning the Scope of Review of a Trial Court's Decision.

The Federal Rules of Civil Procedure define the scope of review of a trial court's decision. FED.R.CIV.P. 52(a) states in part:

> Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge the credibility of the witnesses.

This Court, in discussing the "clearly erroneous" standard in the case of *Zenith Radio Corporation v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), stated at p. 123:

> In applying the clearly erroneous standard to findings of a district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues *de novo*. The authority of an appellate court when reviewing the findings of a judge as well as those of a jury, is circumscribed by the deference it must give to decisions of the trier of fact, who is usually in a superior position to apprise and weigh the evidence. The question for the appellate court under Rule 52(a) is not whether it would have made the findings the trial court did, but whether "on the entire evidence [it] is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 92 L.Ed. 746, 766, 68 S.Ct. 525 (1948).

In the case of *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), this Court held that the Court of Appeals erred in setting aside the District Court's findings of fact. The Court reaffirmed its holding in *Zenith Radio Corporation v. Hazeltine Research, Inc., supra* when it again found that the "clearly erroneous" standard rests upon the unique opportunity afforded the trial judge to evaluate the credibility of witnesses and to weigh the evidence.

Justice O'Connor, writing for this Court, stated at 456 U.S. 857-858:

> Each of those conclusions is contrary to the findings of the District Court. An appellate court cannot substitute its interpretation of the evidence for that of the trial court simply because the reviewing court "might give the facts another construction, resolve the ambiguities differently, and find a more sinister cast to actions which the District Court apparently deemed innocent." *United States v. Real Estate Boards*, 339 U.S. 485, 495 (1950).

In the instant case Petitioner attempted to prove causation based upon the expert medical testimony of three physicians all of whom testified that to a reasonable degree of medical certainty the Plaintiff's condition was caused by the swine flu vaccine. Each of these physicians recited the medical findings upon which he had based his opinion on the ultimate question of causation.

The Court of Appeals, while correctly reciting the Rule 52(a) standard, in practice totally ignored it. It chose instead to adopt a different factual conclusion and disregard the competent expert testimony and medical evidence supporting the trial judge's findings.

The Third Circuit in *Speyer v. Humble Oil & Refining Co.*, 403 F.2d 766 (3rd Cir., 1969) reviewed a decision of the trial court and recognized that it was its responsibility not to substitute findings it could have made had it been the fact finding tribunal, but its sole function was to review the record to determine whether the findings of the District Court were clearly erroneous. There, the Court found at p. 770:

> The basic evidence on liability was introduced by expert witnesses. The matter of weighing the credibility and persuasiveness of expert opinion is the unique function of the trier of fact.

In the instant case, the Court of Appeals must have determined that either all the Petitioner's experts were positively wrong or that their testimony cannot be believed. Such a finding demonstrates either a reweighing of the evidence or a judgment concerning the credibility of the witnesses—areas which are beyond the scope of appellate review and contrary to the existing precedent in this Court and the Sixth Circuit.

Although, *Sentilles v. Inter-Caribbean Shipping Corporation*, 361 U.S. 107 (1959), deals with an appeal from a jury's findings on the issue of causation, the language of this Court's opinion is relevant in light of the standard set forth in *Zenith Radio Corporation v. Hazeltine Research, Inc., supra.* This Court having granted certiorari after the appeals court reversed, discussed at length the province of the fact finder juxtaposed with that of the reviewing court. That language is applicable here:

> The jury's power to draw the inference . . . [of causation] . . . was not impaired by the failure of any medical witness to testify that it was in fact the cause. *Neither can it be impaired by the lack of medical una-*

> *nimity* as to the respective likelihood of the aggravation, or by the fact that other potential causes of the aggrevation existed and were not conclusively negated by the proofs. . . . The members of the jury, not the medical witnesses, were sworn to make a legal determination of the question of causation. They were entitled to take all the circumstances, including the medical testimony, into consideration. . . . The focal point of judicial review is the reasonableness of the particular inference. . . . The very essence of its function is to select from among conflicting inferences and conclusions that which it considers most reasonable. . . . Courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury *could have* drawn different inferences or conclusions or because Judges feel that other results are more reasonable.

361 U.S. at 109-110 (emphasis added). *See also, Gallick v. Baltimore and Ohio Railroad Company,* 372 U.S. 108 (1963); *Bathory v. Procter & Gamble Distributing Company,* 306 F.2d 22 (6th Cir., 1962); *Friedman v. Commissioner of Internal Revenue,* 235 F.2d 86 (6th Cir., 1956).

The decision of the Court of Appeals establishes a dangerous precedent endorsing *de novo* review of findings of fact by the appellate courts. At a time when there is widespread concern by this Court and every circuit over the increase in appeals filed, this decision by the Court of Appeals poses a serious threat to further clog appellate dockets. If this decision is permitted to stand, the Court of Appeals, at least in the Sixth Circuit, will be free to review findings of fact with a view towards selecting the "better" or "preferred" finding. Unsuccessful litigants will have the opportunity to, in essence, have a second trial, a *de novo* review of their claim.

In cases against the United States, such a practice would further erode an injured party's ability to recover for damages. Plaintiffs presently do not have a right to a trial by jury. A successful plaintiff in a trial court in the Sixth Circuit will now have to contend with a new, broader standard of review created by the *Hasler* decision—that of *de novo* review at the appellate level.

Such a policy is particularly onerous where, as here, the Swine Flu Act substitutes the United States as a Defendant for program participants and adopts the procedures of the Federal Tort Claims Act, which normally would not apply in a product liability action against a drug manufacturer.

This case provides this Court with an ideal vehicle for refining and clarifying the "clearly erroneous" standard and at the same time discouraging ill conceived appeals where the only issue is one of fact and where the record on appeal contains adequate evidence supporting the trial court's decision. These reasons justify the grant of certiorari to review the opinion and judgment below.

2. The Decision Below Establishes a Higher Standard of Proof on the Issue of Causation Than Is Required Under the Federal Tort Claims Act and the Swine Flu Act.

The Swine Flu Program Act of 1976, 42 U.S.C. sec. 247b(k)(2) states:

> (2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a

program participant in the same manner and to the same extent that the United States would be liable in any other action brought against it under such sec. 1346(b) and chapter 171, except that—

> (i) the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort and breach of warranty.

The Court of Appeals in its opinion recognizes that:

> Under the Federal Tort Claims Act, we apply the law of the place where the act or omission occurred. 28 U.S.C. sec. 1346(b); *Richards v. United States,* 369 U.S. 1, 82 S.Ct. 585, 7 L.Ed.2d 492 (1962). In this case that place is Michigan.

718 F.2d at 205 n.2.

The Michigan standard of proof on the issue of causation must be applied by the Court of Appeals in reviewing the trial court's decision. The Court of Appeals' holding, however, establishes a higher standard—beyond that of a reasonable medical certainty to an absolute certainty—regardless of the state of the art concerning the etiology of Petitioner's condition. The Court of Appeals has thus overruled or at least overlooked the standard used in Michigan since the last century.

The Court of Appeals' holding is stated as follows:

> The record shows only two facts *with certainty*: (1) a swine flu inoculation protects an individual from flu by causing an immunological reaction; and (2) rheumatoid arthritis may be considered an auto-

> immune disorder. The plaintiff has failed to present any theory linking these facts to show that her immunological reaction to swine flu caused the autoimmune disease from which she suffers.
>
> We find any causal connection between the swine flu inoculation and plaintiff's rheumatoid arthritis merely conjectural. Although, her explanation is consistent with known facts, Mrs. Hasler has not shown that her injury flows in logical sequence from the Defendant's conduct.

718 F.2d 206 (emphasis added).

Several Michigan cases dealing with the standard of proof on the issue of causation demonstrate the Court of Appeals' error in imposing a higher degree of proof than the nature of the case allows. In *Schoepper v. Hancock Chemical Co.*, 113 Mich. 582 (1897) the Michigan Supreme Court long ago recognized that not all cases of negligence will produce proof to exclude all reasonable doubt as to causation. The Court in *Schoepper* stated:

> Defendant's counsel contend that the case of this explosion is a matter of mere conjecture, and it is said by counsel that it is not enough for Plaintiff to prove circumstances consistent with her theory, but that these circumstances, and each of them, must preclude any other rational conclusion. *This we take to be, but another way of stating the proposition that proof must exclude all reasonable doubt. It is hardly necessary to say that no such rule obtains in civil cases.* It is true that where an injury occurs that cannot be accounted for, and where the occasion of it rests wholly in conjecture, the case may fail for want of proof. *Robinson v. Charles Wright & Co.*, 94 Mich. 283; *Redman v. Lumber Co.*, 96 Mich. 545.

> *But such cases are rare and that rule should never be so extended as to result in the failure of justice, or in denying an injured person a right of action where there is room for balancing the probabilities and for drawing reasonable inferences better supported upon one side than the other.*

113 Mich. at 586 (emphasis added). *See also, Emery v. Chesapeake & Ohio Railway Co.*, 372 Mich. 663, 127 N.W.2d 826, 836-837 (1964); *Joba Construction Co. v. Burns & Roe, Inc.*, 121 Mich. App. 615, 329 N.W.2d 760, 770-771 (1982) and *Pippen v. Denison, Division of Abex Corp.*, 66 Mich. App. 664, 239 N.W.2d 704 (1976).

Petitioner's expert medical testimony has already been summarized. This evidence, while not proof positive, beyond a reasonable doubt, does provide a logical cause and effect relationship between Mrs. Hasler receiving the swine flu vaccine and her injury. On the other hand, the defense experts and the Court of Appeals explain the occurrence of Plaintiff's injury at the exact time when you would expect an immune reaction to occur, as a mere coincidence.

The Court of Appeals explains:

> The undisputed medical evidence was that an immunological reaction from an inoculation will usually occur within 10 days. Nevertheless, the inoculation is not the cause of every event that occurs within the 10 day period. Nearly 45 million Americans were inoculated against swine flu. It is not surprising that at least one of those 45 million persons should fall ill shortly after the shot was administered. Without more, this proximate temporal relationship will not support a finding of causation.

718 F.2d at 205.

However, the record on appeal demonstrated much more. The trial court's findings on causation, 517 F. Supp. at 1271, recites a litany of facts which led the trial court to the conclusion that Petitioners had preponderated on the issue of causation. The Court of Appeals has recognized that under the Swine Flu Act and the Federal Tort Claims Act, the Michigan standard for proof of causation must be applied. The Court of Appeals however has in fact disregarded the Michigan standard and imposed a new standard of proof positive on the issue of causation —a standard that would be impossible to meet in any case where differing medical opinions were produced.

Even if, after review of the entire record, the Court of Appeals felt the most compelling explanation is that Petitioner's injury occurring 10 days after the swine flu shot was a mere coincidence, it is not free to reverse the trier of fact on that issue as long as there is a factual basis to support the fact finder's decision.

The Court of Appeals for the Sixth Circuit in the case of *Bathory v. Procter & Gamble Distributing Co.*, 306 F.2d 22 (6th Cir., 1962) reviewed a trial court's findings and applied the correct standard for review on the issue of causation. There, the Court of Appeals stated:

> There was professional evidence that the chemical content of the lotion was such that it *might* be the cause of irritation to the scalp. Plaintiff's doctor testified that the lotion could readily cause an irritation and that it was *"absolutely" possible* that the lotion *could* "trigger" an abnormal loss of hair. We think that the total of this evidence and the justifiable inferences that could be drawn therefrom were adequate to permit a finding that Pin-It was the proximate cause of plaintiff's trouble. We believe that the facts in this case lead with equal facility and

> logical sequence to a justified conclusion that the injury was proximately caused by the product as did the facts found sufficient for such purpose in the case of *Gerkin v. Brown & Sehler Co.*, 177 Mich. 45, 53-54, 143 N.W. 48, 48 L.R.A., N.S., 224.

306 F.2d at 25 (emphasis added).

The Court further stated:

> Defendant emphasizes that plaintiff's professional evidence amounted only to assertions that Pin-It *might, could* or *may possibly* have been the cause involved, and quotes language from decisions to the effect that such evidence has little probative value. Such language must be read in the factual context of the cases wherein it is employed. No Michigan case, however, has held that proof of causation is insufficient because the testimony is phrased in terms of "might" or "could be".

306 F.2d at 26 (emphasis supplied).

The Court of Appeals' decision in *Bathory, supra,* is cited with approval in *Shirley v. The Drackett Products Co.*, 26 Mich. App. 644, 182 N.W.2d 726 (1970), a products liability case in which Plaintiff claimed that upon using a toilet bowl cleaner she suffered severe respiratory injuries from the inhalation of harmful fumes. There, the Court agreed with the trial court and stated:

> To be sure the defendant offered testimony contradicting the testimony offered by the plaintiff's witnesses, but as the trial court noted: "It is not for the court to tell the jury whose testimony is reliable or which testimony is more reliable." Conflicting evidence is, of course, a matter for the jury to determine. The record in the instant case contains

> sufficient evidence, both direct and circumstantial, to support the plaintiff's position.

26 Mich. App. at 650, 182 N.W.2d at 729.

Under the Swine Flu Act and the Federal Tort Claims Act, the Court of Appeals was thus bound to review the trial court's findings on the issue of causation based upon Michigan law. Instead the Court of Appeals has created a new, harsh, nearly impossible burden of proof for plaintiffs which reversed a century of Michigan precedent. Not only has the appellate court failed to follow local law, but it also established a precedent which signals a shift in judicial philosophy redefining the level of proof a plaintiff must offer.

For the first time, a plaintiff is required to establish medical causation absolutely. No longer is the civil case standard of preponderance of the evidence sufficient. Plaintiffs must now prove causation beyond a reasonable doubt, regardless of the state of the art.

In setting forth on this new course, no policy is cited, no scientific evidence is referred to, no good reason is offered as to why the courts should severely restrict the ability of parties to recover for injuries. This case will be referred to in all products liability cases in particular, and negligence cases in general, tried in the District Courts within the Sixth Circuit and perhaps throughout the country. It is a very bad precedent which ignores the dictates of the Swine Flu Act, the Federal Tort Claims Act, Michigan law and the state of medical art.

The record shows quite plainly, and the trial judge found, that the swine flu vaccine was the cause of Petitioner's disease process. The refusal of the Sixth Circuit to respect those facts and those findings and the action of that court in reviewing the record *de novo* and making its own findings on the issue of causation cannot be justified.

CONCLUSION

For these reasons, a Writ of Certiorari should issue to review the judgment and opinion of the Sixth Circuit.

Respectfully submitted,

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March 16, 1984

APPENDIX

Kathleen and Michael HASLER, Plaintiffs-Appellants (82-1126), Plaintiffs-Appellees (81-1584),

v.

UNITED STATES of America, Defendant-Appellant (81-1584), Defendant-Appellee (82-1126).

Nos. 81-1584, 82-1126.

United States Court of Appeals, Sixth Circuit.

Argued April 20, 1983.

Decided Oct. 7, 1983.

Plaintiff brought personal injury suit against Federal Government for damages allegedly resulting from her inoculation with swine flu vaccine. The United States District Court for the Eastern District of Michigan, 517 F.Supp. 1262, Horace W. Gilmore, J., found Government liable, and Government appealed. The Court of Appeals, Boyce F. Martin, Jr., Circuit Judge, held that district court's finding that flu shot was cause of plaintiff's rheumatoid arthritis was clearly erroneous.

Reversed.

1. Federal Courts (Key) 754

District judge's conclusions of law are freely reviewable by Court of Appeals.

2. Federal Courts (Key) 866

District judge's findings regarding negligence and causation are subject to clearly erroneous standard.

3. Federal Court (Key) 853

Finding is "clearly erroneous" when, although there is evidence to support it, reviewing court on entire record

is left with definite and firm conviction that mistake has been committed.

See publication Words and Phrases for other judicial constructions and definitions.

4. Drugs and Narcotics (Key) 21

Although plaintiff's disease developed ten days after she received swine flu vaccination, district court's finding that shot was cause of plaintiff's rheumatoid arthritis was clearly erroneous, absent anything more than temporal connection between shot and onset of disease. Public Health Service Act, § 317, as amended, 42 U.S.C.A. § 247b.

Leonard R. Gilman, U.S. Atty., Detroit, Mich., Debra D. Newman (argued), Trial Atty., Torts Branch, Civ. Div., Jeffrey Alexrad, Director, U.S. Dept. of Justice, Washington, D.C., for United States.

James A. Tucker, David M. Barbour (argued), Detroit, Mich., for Kathleen and Michael Hasler.

Before LIVELY, Chief Judge, MARTIN, Circuit Judge, and MARKEY, Chief Judge.*

BOYCE F. MARTIN, Jr., Circuit Judge.

This appeal consolidates two aspects of a personal injury suit against the federal government for damages allegedly resulting from the plaintiff's inoculation with swine flu vaccine. Kathleen and Michael Hasler sued the United States pursuant to the Federal Tort Claims Act, U.S.C. §§ 1346(b), 2671, *et seq.*, in conjunction with the Swine Flu Program Act of 1976, 42 U.S.C. § 247b (1976). The district court found the United States liable

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*Honorable Howard T. Markey, Chief Judge, United States Court of Appeals for the Federal Circuit, sitting by designation.

under Michigan tort law and assessed damages against the government of $1.5 million for Mrs. Hasler's injuries and $50,000 for Mr. Hasler's derivative claim. *Hasler v. United States,* 517 F.Supp. 1262 (E.D.Mich.1981). The government appeals. In a second order, the court awarded the Haslers four percent per annum interest on the judgment pursuant to 28 U.S.C. § 2411(b). The Haslers appeal this determination.

The Swine Flu Immunization Program of 1976 was an attempt, underwritten by the federal government, to inoculate the entire population of the United States against swine flu. Several cases of swine flu, a type of influenza, were discovered in early 1976 at Fort Dix, New Jersey. Because the government feared that a pandemic, similar to that occurring in 1918, would ensue, Congress enacted legislation on August 12, 1976 implementing an inoculation program. 42 U.S.C. § 247b. Vaccinations began on October 1, 1976; were suspended on December 16, 1976; and then resumed on a limited basis in February, 1977. Nearly 45 million Americans were vaccinated in this time period.[1]

History demonstrates that no flu epidemic occurred during the winter of 1976-77. However, some individuals did experience harmful reactions to their swine flu vaccinations. The Swine Flu Act delineates the legal remedies available for these injured persons. The Act (1) creates a cause of action against the United States for any personal injury or wrongful death sustained as a result of the swine flu inoculation resulting from the act or omissions of a program participant upon any theory of liability that would govern in an action against such

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1. For a more extensive discussion of the history and purpose of the Swine Flu Program, *see Gicas v. United States,* 508 F.Supp. 217, 218-219 (E.D.Wis.1981); and *Hasler v. United States,* 517 F.Supp. 1262, 1265-1266 (E.D.Mich.1981).

program participant including negligence, strict liability in tort, and breach of warranty (42 U.S.C. § 247b(k)(2)(A)) (amended 1978); (2) makes that cause of action the exclusive remedy and abolishes the cause of action against the vaccine manufacturer (42 U.S.C. § 247b(k)(3)) (amended 1978); and (3) makes the procedures of the Federal Tort Claims Act applicable to suits brought pursuant to the Swine Flu Act. 42 U.S.C. § 247b(k)(4) (amended 1978).

Kathleen Hasler received a swine flu vaccination on November 24, 1976 at a local immunization center. Ten days later she developed a high fever, a rash, and pain and stiffness in her joints and muscles. At that time, her treating physician diagnosed her condition as adult onset of juvenile rheumatoid arthritis, known as Still's Disease. In late August, 1977, the treating physician changed his diagnosis to an acute rheumatoid-like condition secondary to the swine flu vaccination. *See* 517 F.Supp. at 1264-1265 for extensive facts.

The district court concluded that Mrs. Hasler had proven that the swine flu vaccine caused her rheumatoid arthritis. The court reasoned:

> In view of the fact that there were symptoms other than those found in the normal case of Still's Disease, namely rash, anemia, heart murmur, protein and blood in the urine, and because rheumatoid arthritis can result from an antibody antigen reaction and there was no significant medical history related to rheumatoid arthritis, it is reasonable for this Court to find as a matter of fact that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is especially true in view of the temporal relationship. The sudden onset of the disease ten days after the

> swine flu shot—a fact which cannot be regarded by this Court as mere coincidence.

Id. at 1271. The court also found that the government, "under the Michigan law of either negligence, implied warranty or strict liability," had breached its duty to provide adequate warnings of potential health risks. *Id.* at 1269.

We consider first whether Kathleen Hasler demonstrated that the swine flu vaccine caused her rheumatoid arthritis. If she failed to prove causation by a fair preponderance of the evidence, then the government is not liable for her injuries, regardless of the inadequacies of its warning. We agree with the district court that causation is "[t]he most difficult and significant issue in this case." 517 F.Supp. at 1269. However, in contrast to the lower court, we find that the plaintiff has not carried her burden of proof.

[1-4] Needless to say, pursuant to Fed. Rule Civ.P. 52(a), findings of fact by a district judge will not be reversed unless "clearly erroneous." Conclusions of law, on the other hand, are freely reviewable by this court. *See United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 526, 81 S.Ct. 294, 297, 5 L.Ed.2d 268 (1961). While it is generally agreed that determinations of negligence and causation present mixed questions of fact and law, this court, following the prevailing view, has long held that a district judge's findings regarding negligence and causation are subject to the clearly erroneous standard. *See, e.g., Downs v. United States*, 522 F.2d 990, 999 (6th Cir.1975) (negligence); *Michael v. United States*, 338 F.2d 219, 221 (6th Cir.1964) (causation); 9 *C. Wright & A. Miller, Federal Practice & Procedure* § 2590 (1971). A finding is clearly erroneous when "although there is

evidence to support it, the reviewing court on the entire record is left with a definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 68 S.Ct. 525, 542, 92 L.Ed. 746 (1948). We are convinced that the district judge made such a mistake when he concluded that "the swine flu shot was the cause of plaintiff's rheumatoid arthritis."

The district court found the following pertinent facts. Kathleen Hasler received a swine flu inoculation on November 24, 1976. Prior to her inoculation she had enjoyed excellent health. In December, 1976, she developed adult onset of juvenile rheumatoid arthritis, known as Still's Disease. The plaintiff also developed a rash, anemia, a heart murmur, and protein in her urine which were "symptoms other than those found in the normal case of Still's Disease." 517 F.Supp. at 1271. The rheumatoid arthritis set in within ten days of the inoculation, the normal time frame for an immunological reaction. The plaintiff suffered a typical antibody and immunilogical response. Every physician agreed that rheumatoid arthritis "can be related to antibody antigen reaction." *Id.*

Given these facts, to conclude that the swine flu vaccination was the cause in fact of Ms. Hasler's injuries would be mere conjecture. "As a theory of causation, a conjecture is simply an explanation consistent with known facts or conditions but not deductible from them as a reasonable inference. . . . On the other hand, if there is evidence which points to any theory of causation, indicating a logical sequence of cause and effect, then there is a judicial basis for such a [causal] determination." *Kaminski v. Grand Trunk W.R. Co.*, 347 Mich. 417, 422, 79 N.W.2d 899 (1956), adopting *City of Bessemer v.*

Clowdus, 261 Ala. 388, 394, 74 So.2d 259 (1954); reaffirmed in *Schedlbauer v. Chris-Craft Corp.*, 381 Mich. 217, 160 N.W.2d 889 (1968).[2] The plaintiff must show that her injury was the "natural and probable result" of the defendant's actions. *Miller v. United States*, 480 F.Supp. 612, 621 (E.D.Mich.1979) (citations omitted). This she has failed to do.

In the present case, the most significant connection between the flu shot and Mrs. Hasler's rheumatoid arthritis is a temporal one. That the district court found this temporal coincidence particularly persuasive is clear: "[I]t is reasonable . . . to find . . . that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is *especially true in view of the temporal relationship*—the sudden onset of the disease ten days after the swine flu shot. . . ." 517 F.Supp. at 1271 (emphasis added). The undisputed medical evidence was that an immunological reaction from an inoculation will usually occur within ten days. Nevertheless, the inoculation is not the cause of every event that occurs within the ten day period. Nearly 45 million Americans were inoculated against swine flu. It is not surprising that at least one of those 45 million persons should fall ill shortly after the shot was administered. Without more, this proximate temporal relationship will not support a finding of causation.

Another factor relied upon by the district court in finding causation was the swiftness and severity with which the condition of the plaintiff, a previously healthy individual, deteriorated. However, medical testimony established that Mrs. Hasler's case was not unique in this

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2. Under the Federal Tort Claims Act, we apply the law of the place where the act or omission occurred. 28 U.S.C. § 1346(b); *Richards v. United States*, 369 U.S. 1, 82 S.Ct. 585, 7 L.Ed.2d 492 (1962). In this case, that place is Michigan.

regard.[3] Additionally the court found that Mrs. Hasler suffered from anemia, rash, heart murmur and other symptoms not found in the "normal case" of Still's Disease. We note, however, the testimony of several physicians that Mrs. Hasler's symptoms, although not present in every case, nevertheless have been commonly associated with Still's Disease.[4]

Finally, the court relied on the fact that "rheumatoid arthritis *can* result from an antibody antigen reaction." 517 F.Supp. at 1271 (emphasis added). While an antibody antigen reaction *can cause* rheumatoid arthritis, there is no showing that it *did cause* the plaintiff's disease in this case. Moreover, the plaintiff must show that any antibody antigen reaction she may have had was a reaction *to the swine flu shot.* Many of the experts testified that there was no medical literature or evidence to support the plaintiff's theory of causation.[5] The record shows only two facts with certainty: (1) a swine flu inoculation protects an individual from flu by causing an immunological reaction; and (2) rheumatoid arthritis may be considered an auto-immune disorder. The plaintiff has failed to present any theory linking these facts to show that her immunological reaction to swine flu caused the auto-immune disease from which she suffers.

We find any causal connection between the swine flu inoculation and the plaintiff's rheumatoid arthritis merely conjectural. Although her explanation is con-

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3. Dr. Barbour—Vol I p. 181; Dr. Frost—Vol I p. 361; Dr. Sigler—Vol I p. 396; and Dr. Slewinski—Vol. II p. 881-882.

4. Dr. Barbour—Vol. I p. 215, 227-229; Dr. McDonald—Vol. I p 261ff-266; Dr. Frost—Vol. I pp. 356, 357, 367; Dr. Sigler—Vol. I p. 390, 408; Dr. Cushing—Vol. I p. 492; Dr. Fernandez—Madrid Vol. I p. 501-502; and Dr. Slewinski—Vol. II p. 874-875.

5. Dr. McDonald—Vol. I p. 263-264; Dr. Frost—Vol. I p. 351; Dr. Cushing—Vol. I p. 447; and Dr. Fernandez—Madrid Vol I p. 506.

sistent with known facts, Mrs. Hasler has not shown that her injury flows in logical sequence from the defendant's conduct. Thus, the plaintiff has not met her burden of proving causation, and the government is not liable to her or her husband for damages. It follows, moreover, that plaintiff's appeal from the judgment interest award is moot.

We add one final note. The government in its brief emphasized the fact that Mrs. Hasler's attorney was the brother of her physician, insinuating foul play. However, there was absolutely no evidence in the record to support such a charge. We consider the government's comments both inappropriate and unprofessional.

Judgment reversed.

Kathleen HASLER and Michael Hasler,
Plaintiffs,

v.

UNITED STATES of America,
Defendant.

Civ. A. No. 78-70130.

United States District Court,
E. D. Michigan, S. D.

July 15, 1981.

A swine flu injection recipient filed action to recover for injuries allegedly suffered as a result of the injection. The District Court, Gilmore, J., held that: (1) the Government breached its duty of providing an adequate warning to recipients of the potential dangers of the swine flu vaccine to its recipients; (2) the consent form which the recipient signed prior to getting the shots did not adequately advise her of the possible risks of the vaccine so as to constitute "informed" consent; (3) the recipient established by a fair preponderance of the evidence that the swine flu shot did indeed cause the rheumatoid arthritis which she suffered; (4) the recipient of the shot was entitled to recover damages in the amount of $1,500,000; and (5) the recipient's husband was entitled to recover damages in the amount of $50,000.

Judgment for plaintiff.

1. Physicians and Surgeons (Key) 16

Swine flu immunization program participant cannot be joined as party defendant, nor can United States implead one as third-party defendant for their contribution or indemnity, since United States assumes full responsibility for any liability of program participant.

2. Federal Courts (Key) 876

In action to recover for injuries allegedly suffered as result of swine flu injection, to resolve liability issue, District Court must look to state law governing negligence and strict liability, since Government is liable for whatever conduct would have been actionable against program participant under law of state or locality where act or omission occurred. 28 U.S.C.A. § 1346(b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

3. Drugs and Narcotics (Key) 18

Sales (Key) 284(1)

Under Michigan law, manufacturer of drug has duty to warn of dangers which he knew of or reasonably should have known of, and failure to do so constitutes not only negligence but breach of implied warranty and imposes strict liability.

4. Drugs and Narcotics (Key) 17

Sales (Key) 284(1)

Warnings given to recipient of swine flu injection that recipient might have sore arm and that "Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people may also have fever, chills, headaches or muscle aches within the first 48 hours," were insufficient to avoid liability for either breach of warranty or negligence, since no reasonable person would consider him or herself to be in any danger whatever from taking drug. 28 U.S.C.A. § 1346(b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

5. Drugs and Narcotics (Key) 17

Consent form signed by recipient of swine flu injection prior to getting shot did not adequately advise her

of possible risks of vaccine so as to constitute "informed" consent. 28 U.S.C.A. § 1346(b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

6. Drugs and Narcotics (Key) 21

In action to recover for injuries allegedly suffered as result of swine flu injection, recipient of injection established that recipient's rheumatoid arthritis was caused by swine flu injection where onset of disease was within time limits for such type of immunological reaction, recipient's reaction was typical antibody and immunological response, rheumatoid arthritis could be related to antibody antigen reaction and recipient and her family had negative health history. 28 U.S.C.A. § 1346(b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

7. Damages (Key) 130(1)

In action to recover for injuries allegedly suffered as result of swine flu injection, recipient of injection was entitled to recover $1,500,000 for pain and suffering, for disability, and for complete change of life-style after recipient contracted rheumatoid arthritis and would face, in future, further hip replacements, knee replacements and surgery on her hands and ankles. 28 U.S.C.A. § 1346 (b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

8. Damages (Key) 133

In action to recover for injuries allegedly suffered as result of swine flu injection, injection recipient's husband was entitled to award of $50,000 for loss of consortium, loss of services and the like, after recipient contracted rheumatoid arthritis as result of receiving injection. 28 U.S.C.A. § 1346(b); Public Health Service Act, § 317 as amended 42 U.S.C.A. § 247b.

Tucker, Barbour & Mack, P.C. by James A. Tucker, David M. Barbour, Detroit, Mich., for plaintiffs.

Stuart Schiffer, Acting Asst. Atty. Gen., Richard A. Rossman, U. S. Atty., Detroit, Mich., Jeffrey Axelrad, Director, Torts Branch by Debra Newman, Thaddeus B. Hodgdon, Trial Attys., Torts Branch, Civil Division, U. S. Dept. of Justice, Washington, D. C., for defendant.

OPINION

GILMORE, District Judge.

This is an action by Kathleen Hasler and her husband Michael Hasler to recover for injuries allegedly suffered as a result of a swine flu injection received by Mrs. Hasler. Mr. Hasler derivatively sues for loss of consortium, loss of services and the like.

On November 24, 1976, plaintiff Kathleen Hasler received a swine flu vaccination under the National Swine Flu Immunization Program at the Penrickton Center for Blind Children in Taylor, Michigan. The swine flu vaccine administered to her was manufactured, formulated, processed, and sold by Merck, Sharp and Dohme, a division of Merck and Company, a program participant pursuant to 42 U.S.C. § 247b. The Penrickton Center for Blind Children was also a program participant pursuant to the statutory section cited above. Jurisdiction is conferred on the Court by the Federal Tort Claims Act, 28 U.S.C. § 1346(b), and the National Swine Flu Immunization Program Act, 42 U.S.C. § 247b.

Prior to her vaccination, plaintiff had seen and heard mass media advertisements that said there was a good possibility of a swine flu epidemic throughout the United States, and that the United States Government was attempting to vaccinate every man, woman, and child in

the country. She testified that she saw President Ford on television telling the American people that everyone should get a swine flu shot, and that she heard nothing about the risks of taking the swine flu shot. She said she felt it was her duty to have a shot to help build immunity in the community, and she was especially concerned about it because she was employed as a receptionist at a pediatric clinic and she feared the possibility of infecting children in the clinic.[1]

Immediately prior to receiving her shot, plaintiff was provided with a registration form which she scanned and signed. She did not read the form. The worker at the clinic told her that the only possible side effect would be some swelling at the site of the shot and perhaps a fever. This form, which was received as Defendant's Exhibit 30, said, with reference to side effects:

> "Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people

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1. There had been a tremendous amount of publicity urging people to take the swine flu vaccination in the fall and early winter of 1976-77. Two exhibits of interest are plaintiff's Exhibit 21, which is a letter to all radio station managers from Theodore Cooper, M.D., Assistant Secretary of Health, urging them to publicize the swine flu and to call upon people to receive their shots. Of particular interest is the fourth paragraph in the letter, which says: "The influenza vaccine we are using has been tested more than any in the past. It is safe and effective and there is no reason to worry about it causing death or illness. There are few reactions to this vaccine. Most people won't have any after effects. Some may get a fever and a sore arm which won't last very long."

Plaintiff's Exhibit 25 is a statement by the President urging Congress to appropriate money for mass inoculation of the people and stating among other things, "Finally I am asking each and every American to make certain he or she receives an inoculation this fall. Inoculations are to be available at schools, hospitals, physicians' offices, and public health facilities. The reaction to the shot, I am told, may mean a few sore arms for a day or two—a very small price to pay for this vital protection."

will also have fever, chills, headaches or muscle aches within the first forty-eight hours.

"As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. . . ."

At the time she took the shot, and prior to December 3, 1976, plaintiff was in excellent health, as was her husband.

Ten days after taking the shot, on December 3, 1976, plaintiff experienced a stabbing pain in the right knee while shopping. A stabbing pain in the left knee followed, and the pain subsequently went to all of her joints. A rash rapidly developed which covered 70 percent of her body. When she got home she was unable to bend her knees to get into the bathtub; she suffered severe pain all night and in the morning went to her employer, a physician, Dr. George Mills, who said she had some kind of serum sickness resulting from the swine flu vaccine.

Her condition continued to worsen and her fever rose to 102 degrees. On December 5, 1976, she was admitted to Oakwood Hospital, and remained there until January 29, 1977. Her symptoms, in addition to the pain, were a rash, spiking fever, sore throat, and limitation of motion of all major joints. Later she developed a heart murmur, anemia, and had protein and blood in her urine.

At Oakwood Hospital she was under the care of Dr. Edward M. Barbour, a board certified internist. In the hospital, her condition got progressively worse, and on her discharge on January 29, 1977, the diagnosis was acute rheumatoid arthritis (Still's Disease), suspected rheumatic fever, or fever of undetermined origin.

After her discharge, plaintiff was bedridden and unable to care for herself. Her condition remained unchanged until the summer of 1977, when she was admitted to Harper Hospital, Detroit, for further diagnostic studies by Dr. Barbour. During the period from her discharge from Oakwood Hospital in January until her admission to Harper Hospital in August, she remained totally immobile. She could do no housework, and had to stay in bed 90 percent of the time.

Mrs. Hasler was an inpatient at Harper Hospital from August 18, 1977, through August 25, 1977, when she was discharged with a diagnosis by Dr. Barbour of acute rheumatoid arthritis secondary to swine flu vaccination. This discharge diagnosis was concurred in by other attending physicians, including interns and residents on the staff at Harper Hospital.

Plaintiff had no hospitalization during 1978, but she was in bed most of the time and her condition worsened. Her sister and her mother took over all of her household chores and she was in constant pain. She had no outside activity.

In February of 1979, Mrs. Hasler was readmitted to Harper Hospital and was told that her right hip had completely deteriorated and would have to be replaced. She was discharged, and the next month, March 1979, returned to Harper Hospital for a total replacement of her right hip. The next year, in August 1980, she returned to the hospital and had a total left hip replacement.

At the time of trial, plaintiff testified that she spends 90 percent of her time in bed. She has been unable to return to work or to do the simplest household chores. She cannot properly care for her 11-year-old daughter. She faces the prospect of a joint replacement in her knees,

and surgery on her hands and ankles. She has constant pain in her neck, back and shoulders. The rash and fever are persistent. Her family relationship has deteriorated terribly and life with her husband has drastically changed.

Mrs. Hasler was determined to be totally and permanently disabled by the Social Security Administration, which assigned the onset date of December 3, 1976 for her disability.

Mr. Hasler, who had been in excellent health prior to the illness of his wife, has developed ulcerative colitis, etiology unknown. His ulcerative colitis has been exacerbated by the condition of his wife.

I

In January of 1976, a number of cases of respiratory disease developed at Fort Dix, New Jersey, and the Center for Disease Control Virology Laboratory identified two of eight throat washings from Fort Dix as swine-like virus, type A/NJ/76. Investigation of the swine flu at Fort Dix revealed five patients in which the swine flu virus was isolated. A total of four cases of A/NJ/76 outside of Fort Dix were diagnosed by serological testing and/or by virus isolation in 1976 in the United States, and two cases were diagnosed in 1977. In February and March of 1976, surveys at Fort Dix were conducted. The Center for Disease Control conducted similar surveys in surrounding civilian populations to determine the spread of the swine flu virus. The survey results produced no recorded evidence of a community spread of swine flu from March 1976 through December 1976.

Throughout February and March 1976, various health officials from the Center of Disease Control began planning swine flu immunization programs aimed at inoculating the entire population. A meeting of these officials

and other distinguished medical persons was held at the White House in March 1976, with President Ford in attendance. Following this meeting, the President announced that he was recommending a mass vaccination program for all Americans. In this announcement, President Ford stated he would request the Congress to appropriate money so that every man, woman, and child could be vaccinated against the swine flu. The special appropriation was authorized by the Congress, and on April 15, 1976, President Ford signed the legislation appropriating $135,000,000 for the Swine Flu Program.

On April 21, 1976, swine flu clinical trials began and a total of 7,590 subjects were enrolled. Field trials indicated that single doses of the vaccine did not work well on children, who had a number of reactions, including high fever. There was much discussion in Washington and elsewhere about the potential liability of drug manufacturers and insurance companies if there was to be mass immunization. Legislative hearings were held and many prominent physicians, including Dr. Albert Sabin and the Health Research Group, opposed the program. They proposed that the vaccine be manufactured and stored until there was evidence of a significant outbreak of the swine flu.

Liability issues were eventually resolved by the Government's assumption of liability for adverse reactions of the vaccine, and on August 12, 1976, President Ford signed into law "The National Swine Flu Immunization Program of 1976."

II

Plaintiff relies upon both the Federal Tort Claims Act, 28 U.S.C. § 1346(b) et seq. and the National Swine Flu Immunization Program Act of 1976, 42 U.S.C. § 247

(b), (hereinafter the Swine Flu Act), to establish liability. However, this Court concludes that liability can be predicated upon the Swine Flu Act alone; therefore, it is not necessary to consider the Federal Tort Claims Act to arrive at a decision.

The Swine Flu Act has as one of its purposes the protection of "program participants' " liability. The Act establishes exclusive procedures for asserting claims against the United States and provides that the United States shall be liable ". . . for personal injury or death arising out of the administration of swine flu vaccine under the Swine Flu Program based upon the act or omission of a program participant." Program participant is defined to include manufacturers, distributors, public and private agencies or organizations, and medical and other health personnel.

[1] The Statute further provides that the liability of the United States "may be based on any theory of liability that would govern an action against such program participants under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty." Thus the United States assumed full responsibility for any liability of a program participant. A program participant cannot be joined as a party defendant, nor can the United States implead one as a third party defendant for contribution or indemnity.

Many swine flu cases, including this one, were consolidated for pretrial purposes before Judge Gesell of the District Court of the District of Columbia as an MDL CASE. Judge Gesell entered a comprehensive pretrial order, in which he stated in significant part:

> ". . . under the Swine Flu Act, the United States is a substitute defendant for program participants

and is therefore liable to the same extent that a program participant would have been liable under the law of the State or locality where the act or omission occurred. . . ."

On motion for summary judgment, Judge Gesell ruled that the following decisions may not be predicates for liability in swine flu cases:

A. The decision to establish a National Swine Flu Immunization Program;

B. The decision to suspend the Program on December 16, 1976, and the timing thereof;

C. The decision to resume the Program on a limited basis in February 1977.

The Court did hold, however, that the liability of the United States for personal injury or death arising from an act or omission of any program participant in the National Swine Flu Immunization Program shall be based upon the law applicable to private persons in the State where the injury occurred, and that possible theories of liability are negligence, breach of implied warranty, breach of express warranty, strict liability, or misrepresentation under ¶ 402B of the Restatement of Torts.

Plaintiff in the present case first contends that the defendant was negligent in the following ways: 1) manufacturing, promoting, and supplying the vaccine without adequate testing; 2) manufacturing, promoting, and selling a defectively designed and manufactured vaccine; 3) inoculating the public without adequate warnings; 4) failing to adequately and timely warn plaintiff of the risk/benefit analysis so that the plaintiff could properly weigh the risks and benefits; and 5) failing to properly and timely warn the medical profession and the public of the risk of danger associated with the swine flu inoculation.

Mrs. Hasler also claims she is entitled to recover on a theory of strict liability, alleging that the swine flu vaccine was defective and dangerous to use because of defective design and manufacture and/or inadequate warnings. She also claims breach of implied warranties of fitness and merchantability resulting in injury and damage to her, and breach of express warranties purportedly contained in labels and advertisements espousing the effectiveness and safety of the vaccine.

[2] To resolve the liability issue, the Court must look to the law of Michigan governing negligence and strict liability, since by virtue of the MDL pretrial order the Government is liable for whatever conduct would have been actionable against a program participant under the law of the state or locality where the act or omission occurred.

In addition, the Swine Flu Act imposed a special statutorily created duty to "fully explain or warn," a departure from which is actionable. Under 42 U.S.C. § 247b(j)(1)(F), the Secretary of HEW was charged with the:

> ". . . Development, and consultation with the National Committee for the Protection of Human Subjects of Biomedical and Behavioral Research and implementation of a written informed consent form and procedures for *assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such a vaccine is administered.*" (emphasis added).

Judge Gesell pointed out in his final pretrial order on page 2:

> "Nothing in the Swine Flu Act itself bars the plaintiff from demonstrating that in a given situation

a program participant as well as the United States had the duty to warn potential vaccinees."

Michigan law governing negligence and breach of implied warranty theories in warnings is set forth in the leading case of *Smith v. E. R. Squibb & Sons,* 405 Mich. 79, 273 N.W.2d 476 (1979). There the Michigan Supreme Court held that:

> "A manufacturer of a prescription drug has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the drug which the manufacturer knows or should know to exist . . . however, this duty has been held to require warnings to the patient when the prescription drug is administered on a mass immunization program; e. g. *Davis v. Wyeth Laboratories, Inc.,* 399 F.2d 121 (CA9 1968). Determination of whether the duty has been breached in the context of a negligence claim necessitates that the warnings given be examined as to their reasonableness under the circumstances." *Id.* at 88-89, 273 N.W.2d 476.

Speaking of breach of implied warranty, the Court stated:

> "Breach of implied warranty, on the other hand is established when plaintiff proves that a product defect attributable to the manufacturer has a causal relationship to the plaintiff's injuries. . . *It is commonly accepted that inadequate warnings alone can constitute a product defect, whether the theory be implied warranty or strict liability in tort. . . As noted by the Court below, it is also generally recognized 'that . . . . under the implied warranty theory, it is not necessary to prove negligence.'*" *Id.* at 89, 273 N.W.2d 476. (emphasis added).

The Court continued:

"However when the factual issue is not whether the product itself is defective, but whether the manufacturer has provided adequate warnings, the existence of a product defect and a breach of duty is determined by the same standard—reasonable care under the circumstances. In the context of a product liability case, it has been said that 'The standard by which a jury determines adequacy is a general negligence standard that liability is created by "conduct that falls below the standard established by the Law for the protection of others against unreasonably great risks of harm" . . . . This is true because the focus is upon the *adequacy* of the warnings regardless of the theory of liability.' " *Id.* at 90, 273 N.W.2d 476.

Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (CA9 1968) cited by the Michigan Supreme Court in *Smith v. Squibb*, supra, involved a 1963 mass immunization program begun by the Idaho Falls Medical Society for poliomyelitis. The Court pointed out that under any theory, breach of implied warranty, strict liability or negligence, liability is avoided only in those situations where the sale is accompanied by proper directions or proper warnings. The Court set forth a balancing test. Where a risk is very minor because there is only an extreme improbability that anything will happen, a warning is not necessary, but in *Davis* the Court rejected Wyeth's contention that the one in a million possibility of a reaction from a vaccine was so minor as so not to create a duty to warn. The Court said:

"When, in a particular case, the risk qualitatively (e. g. of death or major disability) as well as quantitatively, on balance with the ends sought to be achieved,

is such as to call for a true choice judgment, medical or personal, the warning must be given." *Id.* at 129, 130.

[3] It is therefore clear under Michigan law that a manufacturer has a duty to warn of dangers which he knew of or reasonably should have known of, and that the failure to do so constitutes not only negligence but breach of implied warranty, and imposes strict liability.

[4] In this case, the warnings given to the plaintiff were minimal. She was told by the person administering the shot only that she might have a sore arm. The written warning (Defendant's Exhibit 30) stated that "Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people may also have fever, chills, headaches or muscle aches within the first 48 hours." A general disclaimer suggested that with any vaccine or drug the possibility of severe or potentially fatal reaction exists.

In addition, there were inserts in the packages of vaccine which went to physicians, warning of possible neurological injuries. Such warnings were not given to the plaintiff or any recipient of the vaccine, and it is clear from the Government's subsequent admission of liability in cases involving Guillain-Barre Syndrome that there were potential neurological dangers in the vaccine that were not made part of the warning.

The warnings given in this case were so bland that no reasonable person would consider him or herself to be in any danger whatever from taking the drug. In fact, the warning given to plaintiff personally was decidedly "upbeat" and certainly not sufficient to avoid liability for either breach of warranty or negligence.

[5] Moreover, the consent form which Kathleen Hasler signed prior to getting the shot did not adequately advise her of the possible risks of the vaccine so as to constitute "informed" consent.

In *Petty* v. *United States,* No. C 78-4083, United States District Court for the Northern District of Iowa, Judge O'Brien found the Government liable and negligent for failure to provide a satisfactory, informed consent form as required by the Swine Flu Act.

The Court criticized the consent form, stating:

> "A careful look at the required 'informed consent form' . . . shows that it is hardly that. First of all it's called 'registration form'; nowhere do the words 'informed consent' or 'consent' appear. The individual is not advised with respect to his 'rights and remedies' which may arise out of the administration of the vaccine."

The language of that opinion is especially significant when one looks at the identical form signed by plaintiff herein. It is entitled "Registration Form." Attached to it is a form called "Important Information about Swine Influenza 'flu' Vaccine, 'Monovalent'," on the back of which it says: "These vaccines have been field tested and shown to produce very few side effects. Some people who received the vaccine had fever and soreness during the first day or two after vaccination. These tests and past experience with other flu vaccines indicate that anything more severe than this would be highly unlikely."

"As indicated, some individuals will develop fever and soreness after vaccination. If you have more severe symptoms or if you have fever which lasts longer than a couple of days after vaccination, please consult your doctor or a health worker wherever you receive medical care.

"While there is no reason to expect more serious reaction to this flu vaccination, persons who believe they have been injured by this vaccination may have a claim . . ."

This Court can only conclude that informed consent was not an element of the "registration form" signed by the plaintiff here. Looking beyond the disparity between the title of the form and its claimed purpose, and the total absence of the term "informed consent" from the text, the contents of the form do not educate or advise the prospective vaccinee, but merely speculate as to the possible risks. The rights and remedies arising as a consequence of assuming these risks are never discussed. It simply cannot be said that plaintiff was provided with enough information as to the risks, rights, and liabilities to permit her to make an informed judgment prior to receiving the vaccine.

It is therefore clear that, as a matter of fact, the Government, under the Michigan law of either negligence, implied warranty or strict liability, breached its duty of providing adequate warning of the possible potential dangers of the vaccine to its recipients. Liability is thus established in this case.

III

[6] The most difficult and significant issue in this case, and the one on which most trial time was spent is that of causation. That the Government was negligent or breached its implied warranty is clear. The question of causation is not so easily resolved.

Three physicians testified for the plaintiff that there was a causal connection between the injection of the swine flu shot and the crippling disease of plaintiff.

Dr. Edmund Barbour was plaintiff's treating psysician. He is a board certified internist specializing in gas-

troenterology. He is head of the Department of Gastroenterology at Oakwood Hospital in Detroit, and Assistant Head of the Department of Gastroenterology at Harper Hospital in Detroit. He is also Assistant Professor of Clinical Medicine at Wayne State University.

Dr. William McDonald, an associate of Dr. Barbour's, is a rheumatologist who saw plaintiff on a few occasions. He is board eligible (but not board certified) in rheumatology and has been practicing in the field of rheumatology for many years.

Dr. Anthony Sliwinski is board certified in internal medicine and rheumatology, and is head of Rheumatology at the Georgetown University Hospital in Washington, D.C.

All three are well qualified physicians, and all three found a causal connection between plaintiff's problem and the swine flu vaccine.

Defendant presented four equally well qualified physicians: Dr. Philip Frost, a board certified immunologist and Ph. D. in immunology, who consulted with Dr. Barbour; Dr. John Sigler, board certified in internal medicine, and Chief of the Department of Rheumatology at the Henry Ford Hospital; Dr. Ralph Cushing, Associate Professor of Medicine at Wayne State University and Chairman of the Department of Medicine, and Dr. Felix Fernandez-Madrid, Chief of the Rheumatology Section at Harper Hospital and Chief of Rheumatology and Clinical Immunology at the Wayne State University Medical School.

All defense physicians diagnosed Mrs. Hasler's condition as Still's Disease or juvenile rheumatoid arthritis. They said she met a sufficient number of the criteria of the American Rheumatology Association to have rheumatoid arthritis. Although the defendant's doctors testified that the cause of Still's Disease and adult rheumatoid

arthritis is unknown, they nevertheless opined that the swine flu vaccine had nothing whatever to do with plaintiff's illness.

The task of the Court in weighing the testimony of these physicians, all of whom are competent and reputable, is a difficult one.

Dr. Barbour justified his conclusion that the swine flu vaccine caused plaintiff's condition by saying it was a delayed immunological response secondary to a swine flu injection. He stated that this was his opinion to a reasonable medical certainty, noting that antibody reactions can cause the kind of reaction Mrs. Hasler had here. Dr. Barbour reached this diagnosis only after excluding everything else. He said a review of her history and a review of her medical progress and records showed he was faced with an immunological response. He said it took him about a year to come to this conclusion, because he wanted to eliminate every other possibility. His final opinion was that plaintiff's disorder was not rheumatoid arthritis, but a rheumatoid-like disorder arising as an immunological response to a swine flu shot. Dr. Barbour said that, in addition to all of the symptoms of rheumatoid arthritis, plaintiff had a heart murmur, kidney involvement, skin rash and anemia. He said none of these occur in normal rheumatoid arthritis. Dr. McDonald and Dr. Sliwinski supported Dr. Barbour's diagnosis.

Dr. Sliwinski found that plaintiff had an auto-immune reaction in her body, characterized by fever and arthritis. There was skin involvement and evidence of kidney involvement. He pointed out that Mrs. Hasler had a unique set of problems, and many things were happening to her that one would not expect to find in adult onset of juvenile rheumatoid arthritis (Still's Disease). He emphasized that the typical onset of rheumatoid arthritis does

not have fever and skin rash, or red blood cells in the urine. He opined that the most likely cause of her difficulty was the swine flu vaccine, because she was perfectly normal before the shot, was given an immunogen, and now has an immunological disease.

On the other hand, Dr. Frost, an immunologist, testified that he did not believe that the swine flu vaccine could cause Still's Disease, but he stated on the other hand that he could not say that it did not. He said plaintiff had rheumatoid arthritis arising from Still's Disease (juvenile rheumatoid arthritis) and that medicine did not know the cause for such disease. He opined that the swine flu vaccine did not cause Mrs. Hasler's arthritis, that there are no reports in the literature of any swine flu arthritis cases, and that the opinions of Dr. Sliwinski, Dr. Barbour and Dr. McDonald were pure speculation. On cross examination, Dr. Frost admitted that in the study of cases in which swine flu shots were given to people with arthritis, seven of 13 cases had exacerbations after receiving the swine flu shot, but he testified that this is not unusual because arthritis cases get worse and get better.

Dr. Sigler generally concurred with Dr. Frost, but admitted that some people claim that an antigen-antibody response can cause rheumatoid arthritis. He did not concede that himself.

Dr. Cushing opined that the swine flu shot did not cause plaintiff's rheumatoid arthritis. He said no one knows the cause of rheumatoid arthritis but that there is nothing in the literature to show that swine flu shots could cause rheumatoid arthritis. He did concede, however, that rheumatoid arthritis and Still's Disease sometimes can be caused by an auto-immune reaction, and that rheumatoid arthritis and Still's Disease can be the

result of antigen-antibody reactions. He nevertheless contended that the swine flu injection had nothing to do with the sudden onset of plaintiff's condition.

Dr. Fernandez-Madrid supported other defense doctors, testifying that there is no showing that the swine flu shot could cause or did cause or exacerbate rheumatoid arthritis.[2]

Several things impress the Court and impel a conclusion that the plaintiff has carried her burden by a fair preponderance of the evidence by showing that the swine flu shot did indeed cause her arthritis.

First of all, the onset of the disease was within the time limits for such type of immunological reaction. Temporally the reaction started in "text book manner." This was agreed to by all physicians.

Secondly, plaintiff's reaction was a typical antibody and immunological response which usually develops seven to 10 days after a shot is given.

Third, tests given upon admission to the hospital were all normal, but subsequently there was a high spiking fever, rash, anemia, heart murmur, and an inflammatory process throughout the entire body. Moreover, every physician agreed that rheumatoid arthritis can be related to an antibody antigen reaction.

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2. All physicians who testified for the defense said they didn't know the cause of Still's disease or rheumatoid arthritis, but that the swine flu vaccine did not cause them.

Their syllogism seems to be:

1. Plaintiff has rheumatoid arthritis.
2. No one knows the cause of rheumatoid arthritis.

Therefore: Swine flu vaccine cannot cause rheumatoid arthritis. The syllogism speaks for itself.

Finally, the negative health history of plaintiff and her family are significant to the conclusion that the swine flu shot was the causative factor of plaintiff's disease.

In view of the fact that there were symptoms other than those found in the normal case of Still's Disease, namely rash, anemia, heart murmur, protein and blood in the urine, and because rheumatoid arthritis can result from an antibody antigen reaction and there was no significant medical history related to rheumatoid arthritis, it is reasonable for this Court to find as a matter of fact that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is especially true in view of the temporal relationship—the sudden onset of the disease ten days after the swine flu shot—a fact which cannot be regarded by this Court as mere coincidence.

The Court therefore finds that the United States Government must respond in damages.

IV

[7] Now—the consideration of damages. Mrs. Hasler has already incurred $43,000 in medical expenses, and Dr. Barbour testified that her condition will get progressively worse. Plaintiff faces further hip replacements, a knee replacement, and surgery on her hands and ankles. Dr. Barbour stated, without contradiction, that she will require seven to eight hospitalizations in the future, and that each hospitalization will cost between six and ten thousand dollars. Therefore she will have future hospital expenses of from $42,000 to $80,000, in addition to her expenditures of $43,000 to date.

The only expert witness on damages was James Gifford, an economist, who testified for plaintiff. He offered, and the Court received, Plaintiff's Exhibit 28, which was an economic analysis of plaintiff's loss of income and loss of

the value of household work. His unrefuted calculations, which were adjusted for inflation and for interest rates, showed a loss of $811,340 until age 65.

Plaintiff has already been determined by the Social Security Administration to be totally and completely disabled, and all medical testimony is unanimous as to her disability. No one claims that she will ever be able to work again, nor does anyone claim she will ever be able to do reasonable housework.

In addition to the medical expenses and wage and household losses outlined above, the Court must assess a reasonable figure for the pain and suffering she has endured, for her disability, and for the complete change of lifestyle which she has suffered and will continue to suffer for the rest of her life. These intangibles are difficult to determine. But considering the actual wage and medical losses, the Court feels that a reasonable judgment for plaintiff Kathleen Hasler against the United States Government is one million, five hundred thousand dollars ($1,500,000) and will order judgment for that amount against the Government of the United States.

[8] With reference to Mr. Hasler, his testimony indicated that the marriage was never the same after the illness, that no longer can they do the things that they used to do as husband and wife. In addition, Dr. Barbour testified that Mr. Hasler has ulcerative colitis, and that, although the etiology of ulcerative colitis is unknown, it is medically established that stress aggravates ulcerative colitis. The ulcerative colitis is under good control at the moment, but it could flair up.

Considering all of these factors, the Court determines that a reasonable award on a derivative basis to plaintiff Michael Hasler is fifty thousand dollars ($50,000).

This opinion shall constitute the findings of fact and conclusions of law required by F.R.C.P. 52(a).

Plaintiffs may present judgments, add interest, and tax costs.